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| APPLICATION N       | 10.                | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|--------------------|-------------|---------------------------|---------------------|------------------|
| 10/717,237          | <u> </u>           | 11/19/2003  | Jackson Boling Hester JR. | 00587.US1           | 6903             |
| 25533               | 7590               | 03/24/2006  |                           | EXAMINER            |                  |
| PHARM               | IACIA & U          | JPJOHN      | SACKEY, EBENEZER O        |                     |                  |
| 7000 Por<br>KZO-300 | tage Road<br>)-104 |             |                           | ART UNIT            | PAPER NUMBER     |
| KALAM               | AZOO, MI           | 49001       | 1626                      |                     |                  |
|                     |                    |             |                           |                     |                  |

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)  |
|---|---|---|
|   | 10/717,237  | HESTER ET AL.   |
| Office Action Summary   | Examiner  | Art Unit  |
|   | EBENEZER SACKEY   | 1626  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | orrespondence address   |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION (6(a). In no event, however, may a reply be time till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE! | l. ely filed the mailing date of this communication. 0 (35 U.S.C. § 133). |
| Status  |   |   |
| <ol> <li>Responsive to communication(s) filed on</li></ol>  | action is non-final.<br>ace except for formal matters, pro  |   |
| Disposition of Claims   |   |   |
| 4) Claim(s) 1-40 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-40 are subject to restriction and/or expectation and/or expec | vn from consideration.  |   |
| 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the orange Replacement drawing sheet(s) including the correction of the orange and the correction is objected to by the Example 11).  | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj   | 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                         |
| Priority under 35 U.S.C. § 119  |   |   |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau * See the attached detailed Office action for a list of  | have been received. have been received in Application ity documents have been receive (PCT Rule 17.2(a)).   | on No d in this National Stage  |
| Attachment(s)    Notice of References Cited (PTO-892)   Notice of Draftsperson's Patent Drawing Review (PTO-948)   Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   Paper No(s)/Mail Date  | 4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:   |   |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-35 and 40 are, drawn to compounds and composition, classified in class 514, 544, 548, 546, in several subclasses.
- II. Claims 36-39 are, drawn to the use of the compounds/composition in treating various disease states, classified in class 514, several subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as shown in U.S.Patent number 5,565,571.

Additionally, the literature search for the methods would be different as a reference for treating microbial infections would not be in the same reference book as for the instant compounds. Hence, a search of the various groups are therefore, not limited to patent files searching, and would constitute an undue burden on the Examiner.

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Applicants are further requested to elect a specifically disclosed species for search purposes.

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

## Advisory of Rejoinder

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found

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patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the

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product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Julie K. Lyons on 03/17/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone

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number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

(571) 272-1600.

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER

**EOS** 

March 19, 2006

Joseph K. McKane

Supervisory Patent Examiner Art Unit 1626, Group 1600

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**Technology Center 1**